



Introduction to the CEN Standard for Laboratory Biorisk Management

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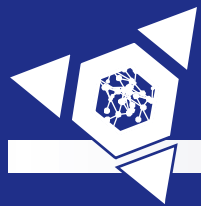
Sandia National Laboratories

Albuquerque, NM USA

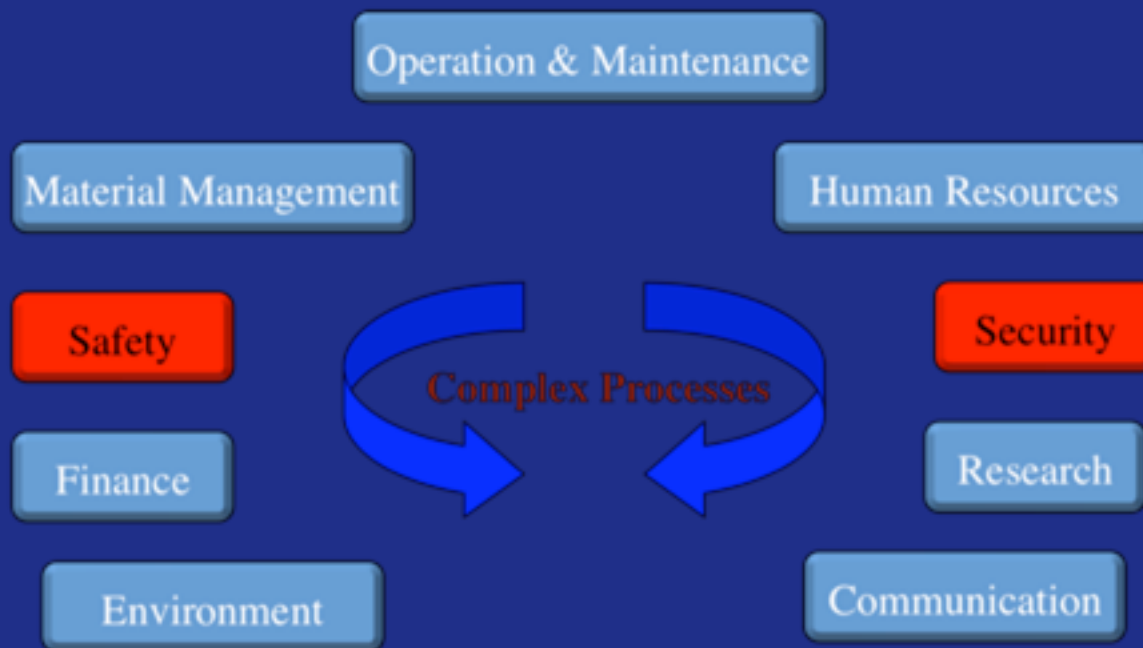
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www.biosecurity.sandia.gov





Laboratory Biorisk Management System





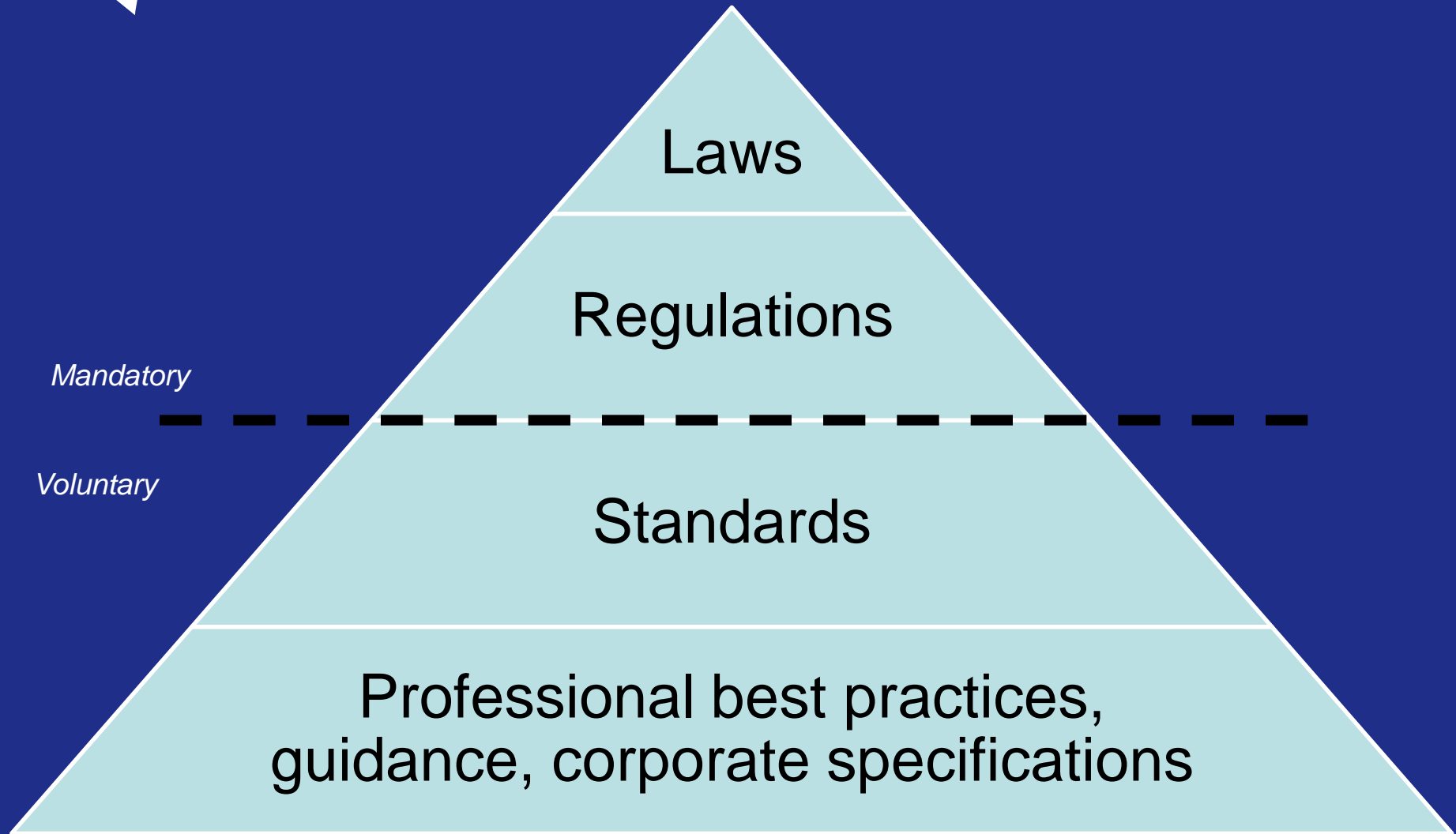
What is Laboratory Biorisk Management?

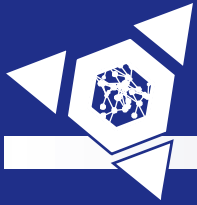
- Biorisk encompasses biosafety and biosecurity, where the hazards are biological agents and their products
- Establishes systems and policies to manage the laboratory biorisk
- Integral in the day-to-day operations of the institute/organization, both in normal times and times of emergency
- **CWA 15793 – Laboratory Biorisk Management Standard**





Standards, Regulations, Best Practice





What is CEN?

- **CEN = Comité Européen de Normalisation (European Committee for Standardization)**
- **31 national members**
- **A major provider of European Standards, technical specifications and technical reports.**
- **The only recognized European organization for the planning, drafting and adoption of European Standards (except for electrotechnology and telecommunication).**
- **CEN Standards have a unique status since they are the national standards in each of its member countries.**

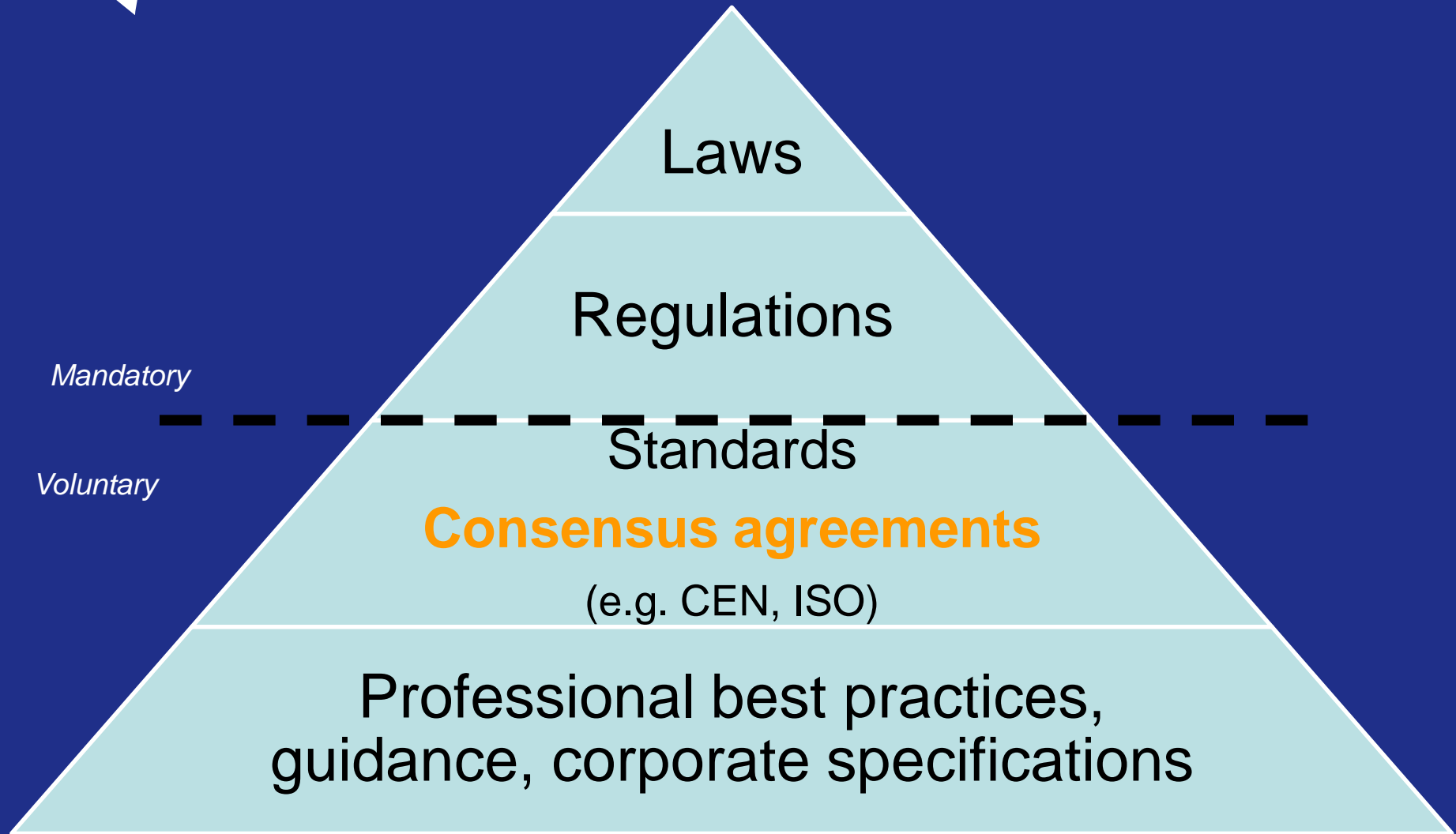


What is a CEN Workshop Agreement?

- **CEN Workshop Agreements (CWAs) are**
 - specifications or standards, drawn up in an open workshop environment
 - voluntary in application
 - established by any interested parties
 - reflects consensus
 - approved by a recognized body
 - meant for common and repeated use
 - Valid for 3 years
- **CWA15793 is 1st and only international standard for any and all laboratories that specifically work with pathogens and toxins**



Standards, Regulations, Best Practice





CWA 15793:2008 Laboratory Biorisk Management

- Developed by 76 participants from 24 countries
- CWA15793 is a **management system standard** consistent with other international standards such as
 - ISO 9001 / 14001 and OSHAS18001
- A management system standard is
 - A framework that integrates best practices and procedures
 - Ensures that an organization can effectively achieve all of its objectives
 - Frequently built around the **Plan, Do, Check, Act** cycle



CWA 15793:2008 Integration

- The CWA15793 Standard is designed to **complement** other management standards
 - ISO9001 (Quality)
 - ISO14001 (Environmental)
 - OHSAS18001 (Occupational Health and Safety)





CWA 15793:2008 Scope

- The CWA Standard is **not** a technical document
- The CWA Standard is **performance-based**
 - Describes what needs to be achieved
 - How to do it is up to the organization
- **Does not replace any national regulations**
 - Compliance with regulations is mandatory under CWA 15793
- **Is a comprehensive blueprint for a laboratory biosafety & biosecurity (biorisk) management program**
 - Risk-based;
 - Applicable to broad range of organizations, not just high containment laboratories or laboratories that work with certain pathogens and toxins



CWA15793:2008 Content

- Extensive definition section
- Biorisk Management Policy
- Hazard identification, risk assessment, and risk control
- Roles, responsibilities, and authorities
- Personnel training, awareness and competence
- Operational control
- Emergency response and contingency plans
- Inventory monitoring and control
- Accident and incident investigation
- Inspection and audit
- Biorisk management review



- **International Approach**
 - Not country specific
 - Based on international, acceptable best practices
 - Local solutions possible
 - The Standard is based around the current WHO Biosafety and Biosecurity Guidelines

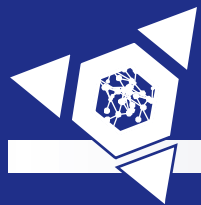
Local solutions for local problems



- **Occupational Health**

4.4.1.6 Occupational health

The organization shall have access to appropriate occupational health expertise and establish an occupational health program commensurate with the activities and risk of the facility.



CWA15793:2008

Key Differences

	CWA 15793	BMBL, LBM etc.
Management System	yes	no
Policy	yes	Generic (if at all)
Continual Improvement	yes	no
Roles & Responsibilities	yes	some
Document Control	yes	no
Auditing	yes	some
Objectives	yes	no
Certification (accredited)	yes	no



CWA15793:2008 Certification??

- CWA is **not integrated** into a formal certification or accreditation system
- A recognized certification/accreditation scheme would ensure the value and consistency of the CWA standard
- International certification/accreditation would strengthen the sustainability of laboratory biorisk management



Certification Stakeholders Meeting February 2010

- 40 individual from 14 countries, EC, and OIE
- **Goals:** To gauge interest in international certification scheme for laboratory biorisk management systems and to identify possible next steps
- **Key discussion points:**
 - Concerns about multiple national and local schemes being developed
 - Learn from current experiences
 - Certification especially valuable for improving biosecurity
- **Consensus conclusions:**
 - Develop certification scheme using CWA15793 as the technical basis
 - Certification scheme should be developed with flexibility
 - Need progress on international scheme before conflicting approaches developed



Typical Accredited Certification of Management Systems

ISO

- Makes the rules

International Accreditation Forum*

- Harmonized world-wide interpretation of the rules

Accreditation Body

- Quality control of the checker

Certification Body

- Checks the implementation of the rules

Organization

- Implements the rules

* IA F includes American Association for Laboratory Accreditation



Laboratory Biorisk Management System (CWA15793)

CEN

- Makes the rules (CWA 15793)

- International harmonization?

Accreditation Body

- ?

Certification Body

- Self-certification, private consultants

Organization

- Some laboratories beginning to implement CWA15793



CWA15793:2008 Implementation

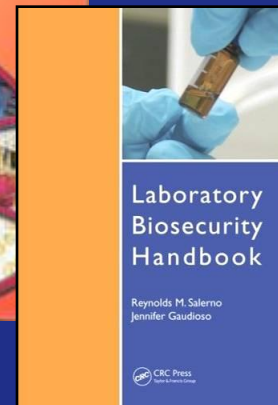
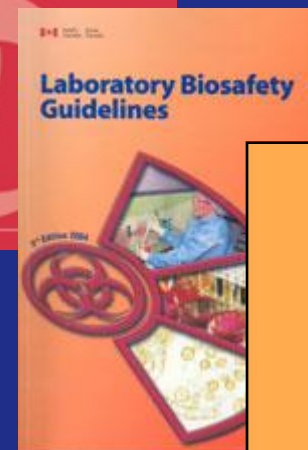
- **CWA is voluntary**
- **Some laboratories in the USA and around the world have begun to implement CWA15793**
- **A Guidance document for CWA 15793:2008 is in draft**
 - Increase the likelihood of CWA 15793 being adopted by the user community;
 - Ensure that users of CWA 15793 are able to understand and implement the recommendations of the CWA;
 - Increase the confidence of stakeholders (including regulators, funding organizations and the community) that there is consistency in the application of CWA 15793 across different laboratories.



International Laboratory Biorisk Management Documents

• Technical

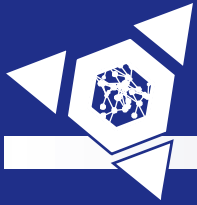
- *Laboratory Biosafety Manual, 3rd Edition*
 - **World Health Organization**
- *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition,*
 - **CDC/NIH: extensive recommendations on biosecurity**
- *Laboratory Biosafety Guidelines, 3rd Edition*
 - **Public Health Agency Canada**
- *Biorisk Management: Laboratory Biosecurity Guidance*
 - **WHO/FAO/OIE joint international biosecurity guidelines**
- *Laboratory Biosecurity Handbook*
 - **Sandia National Laboratories**
- Organization for Economic Co-operation and Development (OECD) is establishing biosecurity guideline



• Management: CEN Workshop Agreements

- CWA 15793 Laboratory Biorisk Management Standard
- CEN WS 55 – CWA 15793 Guidance Document (under development)
- CEN WS 53 – Biosafety Professional Competence (under development)





AMP Model

Biorisk Management =
Assessment **M**itigation **P**erformance



Hazard ID
Risk Assessment



Biorisk Control Measures
Risk Management



Processes
QA/QC
Objectives

Strengthening Biological Risk Management



Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"



Conclusions

Adoption and implementation of the CWA 15793:2008 will be an integral part of the future biorisk management agenda for laboratories worldwide and a necessity to protect people and the environment as well as building community confidence



Questions?

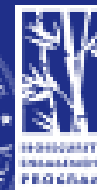
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